FDA 510(k) Premarket Notification

# K121396 DYNAFLEX

**CLEARED**

Aug 14, 2012
97 days to decision

K121396 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k121396/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Aligner, Sequential (NXC) |
| Date received | May 9, 2012 |
| Decision date | Aug 14, 2012 |
| Days to decision | 97 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Dyna Flex** |
| Location | Austin, TX, US |
| Contact | MATTHEW MALABEY |
| 510(k) history | 4 submissions · 4 cleared · 2011-2023 |